K072460

APR 11 2008

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the SMDA of 1990.

1. Submitter's Name	Abbott Vascular, Cardiac Therapies
2. Submitter's Address	26531 Ynez Road, Temecula, CA 92591
3. Telephone	(951) 914-4544
4. Fax	(951) 914-0339
5. Contact Person	Michele Walz
6. Date Prepared	August 30, 2007
7. Device Trade Name	HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device Name	HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wire (K013833, cleared Jan 16, 2002)

11. Device Description

The HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire is a steerable guide wire available in a diameter of 0.0140" and in lengths of 190 cm DOC extendable length and a 300 cm exchange length. The distal tip is offered in a straight shapeable configuration and a pre-shaped "J" configuration. The distal segment of the guide wire is coated with a new lubricious coating to improve guide wire movement in the catheter. The proximal end of the guide wire utilizes SMOOTHGLIDE coating technology.

12. Indication for Use

The HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

13. Technological Characteristics

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate device.

14. Performance Data

In vitro bench testing performance evaluations demonstrated that the HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire met the acceptance criteria and performed comparable to the predicate device. No new safety or effectiveness issues were raised during the testing program and therefore, the HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire may be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Abbott Vascular
c\o Ms. Michele Walz
Regulatory Affairs Associate
26531 Ynez Road
Temecula, CA 92590

APR 11 2008

Re: K072460
Trade Name: Hi-Torque Balance Middleweight Universal II Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 24, 2008
Received: March 25, 2008

Dear Ms. Walz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K072460

Device Names: HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire

Indications for Use: This HI-TORQUE Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

Prescription Use___X___ OR Over-The-Counter_____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Ahmen

(Division Sign-Off)
Division of Cardiovascular Devices

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